REMARKS

In the Office Action dated October 14, 2008, Claims 1-41 are pending. Claims 2, 4, 6, 10-17, 21 and 24-39 have been withdrawn from consideration as directed to non-elected subject matter. Claims 1, 3, 5, 7-9, 18-20, 22-23 and 40-41 are under consideration and are rejected.

This Response addresses each of the Examiner's objections and rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claim Amendments

Independent claims 1, 3 and 22 have been amended to clarify the claimed methods of detection by including a step of comparing the level of LMO4-immunointeractive molecule complex in the cells from the subject or sample under examination with that of control cells or samples, prior to making a relevant determination based on an elevated level of the complex relative to controls. It is respectfully submitted that these amendments do not introduce new matter, as the current language is implicitly supported by the previous version of the claims and by the specification.

Claims 18 and 23 have been amended to delete references to "at least one of the CDRs", which language is objected to by the Examiner. Support for a deimmunized antibody as presently recited in claims 18 and 23 is found in the specification, e.g., page 30, line 2, and pages 30-34.

No new matter is introduced by the foregoing amendments.

Claim Objection

Claim 5 and its dependent claims 7-9 are objected to because claim 5 depends on one of claims 1-4, wherein claims 2 and 4 have been withdrawn from consideration.

In response, claim 5 has been amended to depend from claims 1 and 3 only. Withdrawal of the objection to claims 5 and 7-9 is therefore respectfully requested.

35 U.S.C. §112, Second Paragraph Rejection

Claims 18 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Examiner states that the limitation "said immunointeractive molecule" in line 2 of claim 18 lacks antecedent basis in claim 3.

Applicants have amended claim 18 to delete the reference to claim 3. As amended, claim 18 depends on claim 1 only. The rejection of claim 18 is therefore obviated.

35 U.S.C. §112, First Paragraph Rejection

Claims 3, 5, 7-9, 18, 22-23, and 41 are rejected under 35 U.S.C. §112, first paragraph for allegedly lacking enablement. The Examiner admits that the specification is enabling for a method of detecting an aberrant cell or a predisposition to the development of mammary cells in a subject by screening the levels of a complex formed between the LMO4 protein and an antibody to LMO4. However, the Examiner continues to maintain that the specification does not reasonably provide enablement for the method using a mutant or a variant of an antibody that contains at least one of the CDRs of the variable domains derived from the antibodies to LMO4, including the antibody 16H2.

Claims 18 and 23 have been amended such that the references to CDRs have been deleted, and replaced with a clause which delineates that the subject antibody is deimmunized

with respect to the host into which it will be introduced. Express support for this amendment is found at page 30, line 2 of the specification. Further, the specification provides detailed discussion in relation to the generation of deimmunized antibodies, e.g., on pages 30-34 of the specification.

In view of the amendments to claims 18 and 23 and the instant disclosure, it is respectfully submitted that the subject matter as presently claimed in claims 3, 5, 7-9, 18, 22-23, and 41, is fully supported by the specification, consistent with 35 U.S.C. §112, first paragraph. Therefore, the enablement rejection is obviated and withdrawal thereof is respectfully requested.

35 U.S.C. §102(b) Rejections

Claims 1, 3, 5, 7-9, 18-20, 22-23 and 40-41 are rejected under 35 U.S.C. §102(b) as anticipated by Kenny et al. (*PNAS*, 95: 11256-11262, 1998).

Kenny allegedly discloses a method of detecting the levels of LMO4 protein with an antibody to LMO4 which forms a complex in the tissue section. Kenny does not teach or suggest making a diagnostic determination based on an elevated level of the LMO4-antibody complex. In fact, there is absolutely no disclosure or recognition of a link between an increase in LMO4 levels and the onset of an aberrant cell phenotype. However, the Examiner states that the clause at the end of the claims, "wherein an elevated presence of the complex relative to a normal cell is indicative of an aberrant cell", is interpreted as a mental step and not an active method step.

As submitted above, Applicants have amended independent claims 1, 3 and 22 to specifically recite a step of comparing the level of LMO4-immunointeractive molecule complex in the cells from the subject or sample under examination with that of control cells or

samples, and a step of making a relevant determination based on an elevated level of the complex relative to controls. It is respectfully submitted that the step of comparison, and the step of determination of an aberrant cell phenotype based on an elevated level of LMO4 complex, are both active steps being performed, which are not taught anywhere by Kenny.

Accordingly, it is respectfully submitted that the presently claimed subject matter is not anticipated by Kenny. Withdrawal of the rejection based on Kenny is respectfully requested.

Claims 1, 3, 5, and 18 are also rejected under 35 U.S.C. §102(b) as anticipated by Grutz et al. (*Oncogene* 17: 2799-2803, 1998).

The Examiner's rejection is based on interpretation of "an immunointeractive molecule" as any binding partner of LMO4, as described in the instant specification on page 21. Grutz allegedly discloses NLI1/LDB1 as a Lim-binding protein including LMO4. Grutz also discloses a complex formed between LMO4 and the NLI1/LDB1 protein.

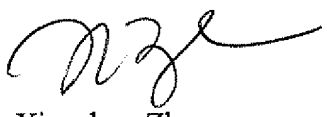
Applicants observe that similar to Kenny, Grutz does not teach or suggest making a diagnostic determination based on an elevated level of LMO4-antibody complex. There is absolutely no disclosure in relation to the notion of changed levels of LMO4-antibody complex in the context of the onset of a neoplastic condition. The citation actually refers to the isolation of an Ldb1/LMO4 complex using a yeast two hybrid screen or expression screen, by virtue of an *in vitro* interaction occurring between Ldb1 and LMO4.

It is respectfully submitted that the presently claimed methods, which include an active step of comparison and a step of determination based on an elevated level of LMO4 complex, are not taught by Grutz. Accordingly, withdrawal of the rejection based on Grutz is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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